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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Steven C. Quay

Docket No.: 2305-2-3

Serial No.: 09/678,591

Group Art Unit: 1614

Filing Date: October 3, 2000

Examiner: Dwayne C. Jones

Title: Long-Acting Oxytocin Analogues for the Treatment and Prevention of Breast Cancer and Psychiatric Disorders

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this communication, and any document being attached hereto,

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Signature

- ☒ Supplemental Information Disclosure Statement
☒ PTO-1449 w/references
☒ Postcard



DOCKET NO. 2305-2-3

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Steven C. Quay

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Examiner: Dwayne C. Jones

For: LONG-ACTING OXYTOCIN ANALOGUES FOR THE TREATMENT AND PREVENTION OF BREAST CANCER AND PSYCHIATRIC DISORDERS

DATE OF DEPOSIT: May 20, 2004

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. Box 1450, ALEXANDRIA, VA 22313-1450


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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98**

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the references listed on the attached Form PTO-1449 be **reconsidered** by the Examiner and made of record as of the original filing date of March 26, 2001.

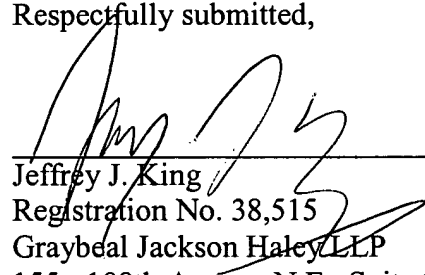
Applicant is complying with the January 29, 2004 request of the Examiner to provide a supplemental list, so that all the references originally cited in the March 26, 2001 Information Disclosure Statement may be properly indicated as being considered. Applicant is providing a "clean" PTO-1449 form along with a copy of all the references that were originally lined out by the Examiner as not being considered because of the omission from the file of hard copies of the references.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information disclosed is, or is considered to be, prior art with respect to the present application or material to patentability as defined in 37 C.F.R. §§ 1.56.

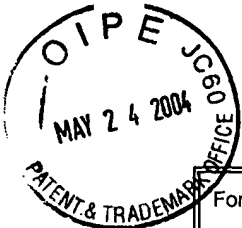
Applicant believes that all the references listed on the original Information Disclosure Statement and PTO 1499 were sent to the United States Patent and Trademark Office on March 26, 2001, and therefore does not believe any fees are required in the submission of this Supplemental Information Disclosure Statement. However, should the Office determine that late submission fees are required for the filing of this Supplemental Information Disclosure Statement, Applicant requests that a telephone conference be conducted to expedite resolution by calling the undersigned at (425) 455-5575.

Respectfully submitted,

Dated: May 20, 2004



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Registration No. 38,515
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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>				Docket Number (Optional) 2305-2-3		Application Number 09/678,591		
				Applicant(s) Dr. Steven C. Quay				
				Filing Date October 3, 2000		Group Art Unit 1616		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS								
EXAMINER INITIALS*		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
	CA	Atke et al., "Uterotonic Activity and Myometrial Receptor Affinity of 1-Deamino-1-Carwba-2-Tyrosine (O-Methyl)-Oxytocin," <u>Acta Endocrinol.</u> 115:155-160, 1987						
	CB	Boucher et al., "Double-Blind, Randomized Comparison of the Effect of Carbetocin and Oxytocin on Intraoperative Blood Loss and Uterine Tone of Patients Undergoing Cesarean Section," <u>J. Perinatology</u> 18:202-207, 1998						
	CC	Bussolati et al., "Immunolocalization and Gene Expression of Oxytocin Receptors in Carcinomas and Non-Neoplastic Tissues of the Breast," <u>Am. J. Pathol.</u> 148:1895-1903, 1996						
	CD	Cobo, E., "Characteristics of the Spontaneous Milk Ejecting Activity Occurring During Human Lactation," <u>J. Perinat. Med.</u> 21:77-85, 1993						
	CE	Cort et al., "Effect of Oxytocin and its Long-Acting Analog on Milk Let-down and Intramammary Pressure in Healthy Lactating Sows," <u>Am. J. Vet. Res.</u> 43:1283-1285, 1982						
	CF	Dansereau et al., "Double-Blind Comparison of Carbetocin Versus Oxytocin in Prevention of Uterine Atony After Cesarean Section," <u>AM. J. Obstet. Gynecol.</u> 180:670-676, 1999						
	CG	Engstrom et al., "Oxytocin Receptor Binding and Uterotonic Activity of Carbetocin and its Metabolites Following Enzymatic Degradation," <u>Eur. J. Pharmacol.</u> 355:203-210, 1998						
	CH	Fay et al., "Oxytocin Does Not Induce A Rise in Intracellular Free Calcium in Human Breast Cancer Cells," <u>Res. Commun. Mol. Pathol. Pharmacol.</u> 103:115-128, 1999						
	CI	Gonser, M., "Labor Induction and Augmentation with Oxytocin: Pharmacokinetic Considerations," <u>Arch. Gynecol. Obstet.</u> 256: 63-66, 1995						
	CJ	Hunter et al.m "Effect of Carbetocin, A Long-Acting Oxytocin Analog on the Postpartum Uterus," <u>Clin. Pharmacol. Ther.</u> 52:60-67, 1992						
EXAMINER				DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.								



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	Applicant(s) Dr. Steven C. Quay	
	Filing Date October 3, 2000	Group Art Unit 1616

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS*		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	DA	Ito et al., "Investigation of the Oxytocin Receptor Expression in Human Breast Cancer Tissue Using Newly Established Monoclonal Antibodies," <u>Endocrinology</u> 137:773-779, 1996
	DB	Kimura et al., "Expression and Immunolocalization of the Oxytocin Receptor in Human Lactating and Non-Lactating Mammary Glands," <u>Human Reprod.</u> 13:2645-2653, 1998
	DC	Mena, F., "Central Effects of Catecholamines Upon Mammary Contractility in Rats Are Neurally Mediated," <u>Neuroendocrinology</u> 61: 722-730, 1995
	DD	Murrell, T.G.C. "The Potential for Oxytocin (OT) to Prevent Breast Cancer: A Hypothesis," <u>Breast Cancer Res. Treat.</u> 35:225-229, 1995
	DE	Murrell, "Epidemiological and Biochemical Support for a Theory on the Causes and Prevention of Breast Cancer," <u>Med. Hypotheses</u> 36:389-396, 1991
	DF	Nass et al., "The Biology of Breast Cancer," <u>Hematol. Oncol. Clin. North Am.</u> 13:311-332, 1999
	DG	Newton, N., "The Quantitative Effect of Oxytocin (Pitocin) on Human Milk Yield," <u>Ann. N.Y. Acad. Sci.</u> 652:481-483
	DH	Norström et al., "Contractile Effect of Oxytocin and 1-Deamino-1-Carba-2-Tyrosine (0-Methyl)-Oxytocin in Myometrial Tissue from Non-Pregnant and Term Pregnant Women," <u>Acta Endocrinol.</u> 122:566-568, 1990
	DI	Orhue, A., "Incremental Increases in Oxytocin Infusion Regimens for Induction of Labor at Term in Primigravidas: A Randomized Controlled Trial," <u>Obstet. Gynecol.</u> 83:229-233, 1994
	DJ	Planchon et al., "Alteration of Prostaglandin E Receptors in Advanced Breast Tumour Cell Lines," <u>Mol. Cell. Endocrinol.</u> 111:219-233, 1995
	DK	Sapino et al., "Oxytocin Receptor Within the Breast: Biological Function and Distribution," <u>Anticancer Res.</u> 18:2181-2186, 1998

EXAMINER	DATE CONSIDERED
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							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	EA	Sapino et al., "Oxytocin Enhance Myoepithelial Cell Differentiation and Proliferation in the Mouse Mammary Gland," <u>Endocrinology</u> 133:838-842, 1993
	EB	Satin et al., "Factors Affecting the Dose Response to Oxytocin for Labor Stimulation," <u>Am. J. Obstet. Gynecol.</u> 166:1260-1261, 1992
	EC	Satin et al., "High-Dose Oxytocin" 20-Versus 40-Minute Dosage Interval," <u>Obstet. Gynecol.</u> 83: 234-238, 1994
	ED	Silcox, et al., "Transfer of Carbetocin into Human Breast Milk," <u>Obstet. Gynecol.</u> 82:456-459, 1993
	EE	Taylor et al., "Interaction of Vasopressin and Oxytocin with Human Breast Carcinoma Cells," <u>Cancer Res.</u> 50:7882-7886, 1990
	EF	Van Dongen et al., "Ascending Dose Tolerance Study of Intramuscular Carbetocin Administered After Normal Vaginal Birth," <u>Eur. J. Obstet. Gynecol. Reprod. Biol.</u> 77:181-187, 1998
	EG	Vilhardt et al., "Interaction of Chymotrypsin with Carbetocin ([1-Deamino-1-Monocarba-2-O-Methyltyrosine]-Oxytocin)," <u>Pharmacol. Toxicol.</u> 81:147-150, 1997

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